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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/789,358

02/26/2004

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44928.000018

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500 7590 12/10/2008  
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EXAMINER

SHAFFER, RICHARD R

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

12/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/789,358	<b>Applicant(s)</b> GANZ ET AL.	
	<b>Examiner</b> Richard Shaffer	<b>Art Unit</b> 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 40-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

It is not possible to know how the dimensions of a particular patient or radiographic data therefrom structurally limit the bone graft of claim 1. Thus the claims are deemed indefinite in scope.

### ***Claim Rejections - 35 USC § 101***

The amendments to the claims file don March 25<sup>th</sup>, 2008 are acknowledged and accepted by the examiner. The corresponding 35 U.S.C. 101 rejections have been overcome and are hereby withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-14, 17, 18, 20, 24, 25, 27-31, 33, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by McKay (US Patent 5,972,368).

McKay discloses a bone graft composite comprising a demineralized bone matrix (**Column 9, Lines 36-37**); at least one hole corresponding to either or both of an intended position of an implant base and/or an attachment device; at least one feature (**19**) allowing the bone graft to be held by a gripping tool; the bone graft comprising a calcium phosphate ceramic (**Column 10, Lines 9-10**); further comprising channels or patterns on a surface of the bone graft (threads); further comprising an additive in the form of bone morphogenic protein; a resorbable polymer in the form of polylactic acid (**Column 9, Lines 43-44**); and wherein the graft is sterile (**Column 7, Line 59**); wherein the bone graft comprises a crestal region (**18**) suitable to augment a crest of the alveolar ridge and a first side region (**13**) suitable to augment a first side of the alveolar ridge; the crestal region having a flat portion and a curved portion (edge of surface **18** and surface **13**); wherein the crestal region further has an internally angled portion A.

Concerning the limitations of claims 8, 9 and 36, it is noted that the device of McKay appears to be substantially identical to the device claimed, although not disclosed as produced by the same process, therefore the burden is upon the Applicant to come forward with evidence establishing an unobvious difference between the two. *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983).

Concerning the limitations of claim 12, it is noted that the device picture in **Figure 1** of McKay shows an orifice (**19**) and an orifice (**O**). The surface into which orifice (**O**)

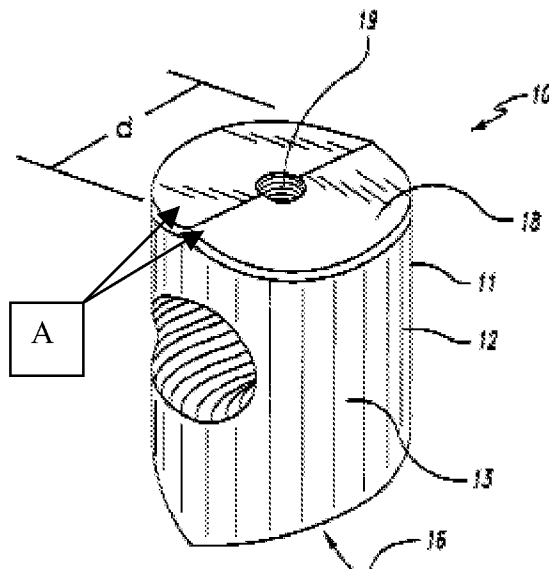
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extends could be considered a bone-facing surface and that into which (19) extends could be a non-bone-facing surface. Because the size of orifice (O) is larger than that of (19), it has a greater porosity.

With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over McKay which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp*, 218 USPQ 781 (CCPA 1983).

Finally, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).



Claims 1, 19, 21, 22, 26, 37 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Khandkar et al (US Patent Application Publication 2003/0009225).

Khandkar et al disclose a bone graft suitable to augment a sinus comprising both a nonresorbable, synthetic ceramic material and resorbable materials (in the form of a coating) in different proportions in different places within the bone graft (**Paragraph 0035**). Concerning the limitation “particles jointed together to form a three dimensionally interconnected matrix, all matter, including demineralized bone and polymers is comprised of particles. For this reason, the Examiner contends that the graft comprising a matrix of particles joined to each other forming a three-dimensionally interconnected network

Claims 1 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al (US Patent 6,200,347).

Anderson et al disclose a composite bone graft (**Figure 27**) suitable to augment a sinus, wherein the bone graft comprises demineralized bone matrix (**100**) in a rigid form and channels (**102**) which extend into an interior of the bone graft.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKay as applied to claim 1 above, and further in view of the following. All matter,

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including demineralized bone and polymers is comprised of particles. For this reason, the Examiner contends that the graft comprising a matrix of particles joined to each other forming a three-dimensionally interconnected network where the particles are polymeric, is inherent to the disclosure of McKay.

Hence, McKay teaches all of the limitations of the present invention except the mode of the pore size being between 10 microns and 25 microns; and the porosity being between approximately 0.2 and approximately 0.6.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone graft of McKay such that the mode of the pore size is between 10 microns and 25 microns; and the porosity is between approximately 0.2 and approximately 0.6, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKay as applied to claim 31 above, and further in view of the following. McKay teaches all of the limitations of the present invention except the polymer being a comb polymer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a comb polymer in place of the polylactic acid polymer disclosed, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

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Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKay as applied to claim 31 above, and further in view of the following. McKay teaches all of the limitations of the present invention except the polymer being a comb polymer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a non-resorbable polymer in the device of McKay, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Khandkar et al as applied to claim 37 above, and further in view of McKay. Khandkar et al. teach all of the limitations of the present invention except the bone graft matrix further including additives, the composition of the additives varying from one place to another.

McKay teaches a bone graft including bone morphogenic protein the distribution of which may be varied.

It would have been obvious to one having ordinary skill in the art at the time of the present invention to incorporate bone morphogenic protein into the matrix of Khandkar et al. to improve the acceptance of the graft in vivo.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140



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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 8-10, 13-26 and 29-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 11, 12, 14-16, 20-28 and 32-39 of copending Application No. 10/789,367. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the claims is in their intended use.

The manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art or copending apparatuses satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Further, it is well known in the art to shape an implant according to the anatomy in which it is intended to be placed against or to fill. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to shape a bone graft in either an alveolar ridge-shape or a sinus-cavity shape as an obvious matter of designing an implant for an intended location.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The provisional rejection of claims 1, 13, 14-16, 19-21, 23-26 and 29-36 as being unpatentable over claims 93-102 and 104-122 of Application No. 10/789,439 is withdrawn due to 10/789,439 being currently abandoned and therefore is not copending with the instant application.

### ***Response to Arguments***

Applicant's arguments filed on March 25<sup>th</sup>, 2008 have been fully considered but they are not persuasive.

In regard to remarks directed towards the rejection of claims 8 and 9 under 35 U.S.C. 112, 2nd paragraph, applicant appears confused as to the grounds of rejection. The claims are not rejected for being non-enabled, but rather due to an indefinite scope. One having ordinary skill in the art would not reasonably understand the scope of the claims when merely setting forth "dimensions are chosen based on dimensions of bone in a patient."

In regard to applicant's remarks directed towards the 35 U.S.C. 102(b), 102(e) and 103(a) rejections, the inclusion of the limitation "at least partially ridge-shaped graft" is not sufficient to overcome the prior art references. At least partially allows any part of the graft that matches an alveolar ridge to read upon the claim. Clearly "a part" of the graft matches "a part" of an alveolar ridge in some person or animal.

In regard to the provisional double patenting rejection, as explained in the current Office Action, merely shaping an implant to match a desired anatomy of a person is well-known in the art and is neither novel nor non-obvious.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/

Examiner, Art Unit 3775

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733